

### REMARKS

This Response is made to the final Office Action dated May 15, 2008. Claims 94-116 are pending in this case. Favorable reconsideration is respectfully requested.

Applicants strongly disagree with the Examiner's action in deeming this Office Action as a final action. In Applicants' previously submitted Amendment, new claims 114-116 were being presented for the first time. Applicants strongly believe that these claims are distinct from previous claims and that these claims are also patentably distinct from the art of record. In making this Office Action final, the Examiner has restricted Applicants' ability to argue the patentability of these claims.

Claims 94-116 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,152,946 to Broome et al. (the "Broome patent") in view of U.S. Patent No. 5,800,457 to Gelbfish (the "Gelbfish patent"). Claims 114-116 are directed to the combination of a frame assembly and filter element. Claim 115 requires each strut of the frame assembly to have a proximal end and a distal end, the proximal ends of the struts being attached to a proximal collar and the distal ends being attached to a distal collar. Applicants believe that this particular structure is not shown in the Broome patent or Gelbfish patent. The Examiner has taken the position that the element referred to as the mouth 28 of the frame 24 in the Broome patent constitutes a collar. Claim 116 requires each peak region of the filter element to be attached to a **strut** of the frame assembly. Since the Examiner has taken the position that the mouth 28 constitutes one of the **collars**, the mouth 28 cannot constitute a strut of the frame assembly. The Broome patent clearly shows the filter element attached to the mouth 28 or collar, as the Examiner has interpreted the Broome patent. Therefore, the filter 22 of the Broome patent would not be considered attached to a strut of the frame assembly, as recited in claim 116, but rather, is attached to a collar 28. This is not the structure recited in claim 116. The Gelbfish patent also lacks the particular structure recited in claim 116. Accordingly, the combination of the Gelbfish patent with the Broome patent fails to disclose the particular structure recited in claim 116. Applicants submit that claim 116 should be allowed or the

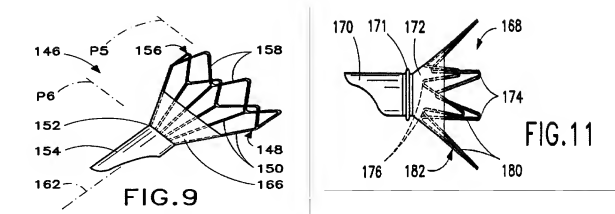
finality of the present Office Action should be withdrawn and new grounds for rejection, if any, should be presented at least as to claim 116.

Applicants again strongly disagree with the Examiner characterization of the Gelbfish patent since this patent merely discloses a frame wire component 156 formed in a zig-zag pattern (Figure 10), not a filter element **made from a filter membrane** as recited in claims 94-116. The presently defined invention of claims 94-116 is specifically directed to the membrane portion of the embolic protection device which has a plurality of openings adapted to allow blood to flow therethrough but to capture embolic debris larger than the size of the openings and contain the debris within a storage reservoir formed from the membrane. The membrane shown in the Gelbfish patent does not perform this function, but rather, simply acts as a **solid barrier** to direct blood flow and embolic material into a catheter used to capture the embolic material. A single, large opening, adjacent to this continuous web or film 166 and membrane 172, is used in the Gelbfish patent to direct blood flow into a debris removal instrument that is used to draw fluid and collected material out of the patient utilizing suction. This single opening of the Gelbfish membrane does not capture embolic debris larger than the size of the opening and contain the debris within a storage reservoir formed from the membrane, as is recited in all of the claims. If the embolic material was larger than this single opening, then the debris removal device of Gelbfish would simply get clogged.

The web or film 166 and membrane 172 of the Gelbfish device lacks a plurality of perfusion openings. In fact, the Gelbfish patent actually teaches away from the use of perfusions openings in the web or film 166 and membrane 172 since the web or membrane is designed to enhance "the transmission of suction forces during a debris removal operation" (see column 11, lines 66-67 of the Gelbfish patent). Therefore, there are no perfusion openings in this "web or film 166" and "membrane 172" since this membrane must remain liquid impermeable in order to enhance the transmission of suction forces. Multiple openings in the Gelbfish membrane would inhibit the development of needed suction forces. Therefore, the use of a plurality of perfusion

openings in the Gelbfish membrane would thwart the ability of the Gelbfish device to capture embolic material and create a suction that is needed to remove both the blood and embolic debris. Therefore, one skilled in the art would simply not look to the Gelbfish patent in solving the problems solved by the currently claimed invention since the Gelbfish membrane is used simply as a solid barrier to direct blood flow into another catheter that collects any embolic material entrained in the blood. Accordingly, the Gelbfish patent fails to disclose the filter element of the present claimed invention.

The position taken by the Examiner, namely, that "Gelbfish teaches an embolic filter with an edge of a sinusoidal configuration with valleys and peaks of different depths" only relates to the wire frame that supports the "web or film 166" or "membrane 172." The web 166 and membrane 172 in the Gelbfish patent are all shown as components having a straight leading edge and lack a plurality of with n. Figures 9 and 11 of the Gelbfish patent are reproduced below:



All of the webs or membranes disclosed in the Gelbfish patent have straight edges which are clearly shown in these figures above. Moreover, the Gelbfish does not teach that the web or membrane can be formed with the wire pattern shown in Figure 10. Rather, the Gelbfish patent states the following at column 11, lines 64-66:

Filter body 148 is provided with a web or film 166 which renders the filter body liquid impermeable at least at its downstream side. Web or film 166 could be made long enough to cover or envelope prongs 150 and zig-zag element 156.

Therefore, the Gelbfish patent does not teach a filter membrane or web that has an edge configured in the shape shown in Figure 9. Rather, the web or membrane is simply extended upward to cover the frame wire as is depicted in Figure 11 above.

Applicants submit that the Broome patent fails to disclose the structure of the pending claims was admitted by the Examiner in paragraph 2 of the previous final Office Action. Accordingly, one skilled in the art would not look to combine the Gelbfish patent with the Broome patent in the first place. Applicants respectfully request the Examiner to withdraw the obviousness rejections against claims 94-116.

In view of the foregoing, it is respectively urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Please charge any fees payable in connection with this response to Deposit Account No. 06-2425.

Respectfully submitted,  
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